IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

JENNIFER BRIDGES, *et al*	§	
	§	
Plaintiffs,	§	
	§	
V.	§	Civil Action No. 4:21-CV-01774
	§	
THE METHODIST HOSPITAL D/B/A THE METHODIST HOSPITAL SYSTEM, AND HOUSTON METHODIST THE WOODLANDS HOSPITAL,	§	
	§	
Defendants.	§	

DECLARATION OF DR. PETER A. McCULLOUGH, MD, MPH

I, Peter McCullough, hereby declare:

1. I am over 18 years of age, of sound mind, and in all ways capable of making this Declaration. The facts stated in this declaration are within my personal knowledge and are true and correct. I could and would testify competently to these facts if called upon to do so.

2. I submit this Declaration in support of the Bridges Plaintiffs motion for temporary restraining order in Civil Action No. 4:21-CV-01774 in the Southern District of Texas.

3. After receiving a bachelor's degree from Baylor University, I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a master's degree in public health at the University of Michigan.

4. I am board certified in internal medicine and cardiovascular disease and hold an additional certification in clinical lipidology, and previously echocardiography. I am on the medical staff at Baylor University Medical Center and Baylor Jack and Jane Hamilton Heart and Vascular Hospital, in Dallas, Texas. I am also on staff at Baylor Heart and Vascular Institute, which promotes cardiovascular research and education. I practice internal medicine and clinical cardiology as well as teach, conduct research, and I am an active scholar in medicine with roles as an author, editorialist, and reviewer at dozens of major medical journals and textbooks. I am Professor of Medicine at Texas A & M University School of Medicine, Baylor Dallas Campus.

5. I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont School of Medicine) as well as academically oriented community health systems. I spearheaded the clinical development of *in vitro* natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and mortality after myocardial infarction. I have contributed to the understanding of the epidemiology of chronic heart and kidney disease through many manuscripts from the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure, and chronic cardiorenal syndromes. I participated in event adjudication (involved attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of anti-diabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments. I have served as the chairman or as a member of over 20 randomized trials of drugs, devices, and clinical strategies. Sponsors have included pharmaceutical manufacturers, biotechnology companies, and the National Institutes of Health.

6. I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my work on the role of chronic kidney disease as a cardiovascular risk state. I have over 1,000 related scientific publications, including the "Interface between Renal Disease and Cardiovascular Illness" in Braunwald's Heart Disease Textbook. My works have appeared in the New England Journal of Medicine, Journal of the American Medical Association, and other top-tier journals worldwide. I am an associate editor of the American Journal of Cardiology and the American Journal of Kidney Diseases. I have testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee, and the Texas Senate Committee on Health and Human Services.

7. I am a Fellow of the American College of Cardiology, the American Heart Association, the American College of Physicians, the American College of Chest Physicians, the National Lipid Association, and the National Kidney Foundation. I am also a Diplomate of the American Board of Clinical Lipidology.

8. In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to the emerging problem of cardiorenal syndromes. I am the President of the Cardiorenal Society of America, an organization dedicated to bringing together cardiologists and nephrologists and engage in research, improved quality of care, and community outreach to patients with both heart and kidney disease.[1]

[1] *See* http://www.cardiorenalsociety.org/.

9. I am the current President of the Cardiorenal Society of America, a professional organization dedicated to advancing research and clinical care for patients who have combined heart and kidney disease. I am the Editor-in-Chief of *Cardiorenal Medicine*, a primary research journal listed by the National Library of Medicine which is the only publication with a primary focus on research concerning patients with combined heart and kidney disease. Finally, I am the Editor-in-Chief of *Reviews in Cardiovascular Medicine*, a widely read journal that publishes reviews on contemporary topics in cardiology and is also listed by the National Library of Medicine.

10. My appended *curriculum vitae* further demonstrates my academic and scientific achievements and provides a list of publications authored by me in the past 30 years.[2]

11. Since the outset of the pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published "Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection," the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the *American Journal of Medicine* and updated in *Reviews in Cardiovascular Medicine*.[3] I have 40 peer-reviewed publications on the COVID-19 infection cited in the National Library of Medicine. Through a window to public policymakers, I have contributed extensively on issues surrounding the COVID-19 crisis in a series of OPED's for *The Hill*. I testified on the SARS-CoV-2 outbreak in the U.S. Senate Committee on Homeland Security and Governmental Affairs on November 19, 2020. I testified on lessons learned from the pandemic response in the Texas Senate Committee on Health and Human Services on March 10, 2021, and on early treatment of COVID-19 the Colorado General Assembly on March 31, 2021. Additionally, I testified in the New Hampshire Senate on legislation concerning the investigational COVID-19 vaccine on April 14, 2020. My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that of infectious disease specialists, is approximately 18 months old. I have

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[2] Exhibit 1.

[3] McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805 available at https://pubmed.ncbi.nlm.nih.gov/32771461/; McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Rev Cardiovasc Med. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID:33387997 available at https://pubmed.ncbi.nlm.nih.gov/33387997/.

formed my opinions based on my direct clinical experience with acute and convalescent COVID-19 cases as well has closely following the preprint and published literature on the outbreak. I have specifically reviewed all the key published rare cases and reports concerning possible recurrence of SARS-CoV-2.

12. Additional details regarding my training and experience are contained in the true and correct copy of my curriculum vitae attached to this Declaration as Exhibit 1.

13. The following statements are based on my years of training, experience, and medical studies. The articles and documents attached are commonly referred to by professionals like myself and I consider them to be authoritative in my field.

14. Of the currently available vaccines for COVID-19 in investigational use in the United States have none have received final full approval from the FDA. Rather, each one of the COVID-19 vaccines is an "unapproved product" that has been granted EUA.[4] The FDA itself refers to the COVID-19 vaccines as "investigational products."

15. The investigational SARS-CoV-2 vaccines manufactured by Pfizer and Moderna contain laboratory synthesized mRNA in a lipid package and theadeno viral DNA in JNJ in viral vector. This mRNA/adeno viral DNA enters the host's cells and takes over the cells causing them to produce the Wuhan spike protein which elicits the development of antibodies.[5] The Wuhan spike protein, independent of the SARS-CoV-2 virion, has been demonstrated to be pathogenic or damaging to blood vessels, organs (brain, heart, lungs, liver, bone borrow) and to be directly thrombogenic by causing hemagglutination and thrombosis. The human host cells respond to the Wuhan spike protein and elicit cell signaling otherwise known as inflammation.[6] The Wuhan spike protein is produced in an uncontrolled fashion without limits on duration. The mRNA/adeno viral DNA vaccines may also affect the host cells which may result in cellular dysfunction and death.[7] Researchers in the cited study recommend that the long-term consequences be monitored carefully for these experimental vaccines, especially when they are administered to otherwise healthy individuals.[8] Scientists further conclude that further investigations on the effects of the SARS-CoV-2 spike protein on human cells and appropriate experimental animal models are warranted.[9]As a medical

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[4] Exhibit 2.

[5] Exhibit 3: Suzuki YJ, Gychka SG. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines. *Vaccines (Basel).* 2021;9(1):36. Published 2021 Jan 11. doi:10.3390/vaccines9010036.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.* ("However, we need to consider their long-term consequences carefully, especially when they are administered to otherwise healthy individuals as well as young adults and children. In addition to evaluating data that will become available from SARS-CoV-2 infected individuals as well as those who received the spike protein-based vaccines, further investigations of the effects of the SARS-CoV-2 spike protein in human cells and appropriate animal models are warranted.")

researcher and practitioner, this study, and others credibly informs me that these mRNA/adeno viral DNA vaccines are not safe for their intended use.

16. The trials relied upon for EUA by the FDA excluded large groups because of lack of expected efficacy and safety concerns. These groups included: COVID-19 recovered, suspected COVID-19 recovered, those with positive COVID-19 serologies, pregnant women, and women of childbearing age who could not ensure contraception. Since these groups were excluded for the trials, the EUA vaccines should not be administered since good clinical practice (GCP) never encourages use of untested, unproven, and potentially unsafe products in excluded groups from randomized registrational trials.

17. The fact that the safety of these vaccines is questionable is not controversial. For example, a consent form from a respected medical institution states, "There is limited information known about the safety and effectiveness of using this vaccine."[10] It goes on, "The Moderna COVID-10 Vaccine is still being studied in clinical trials."

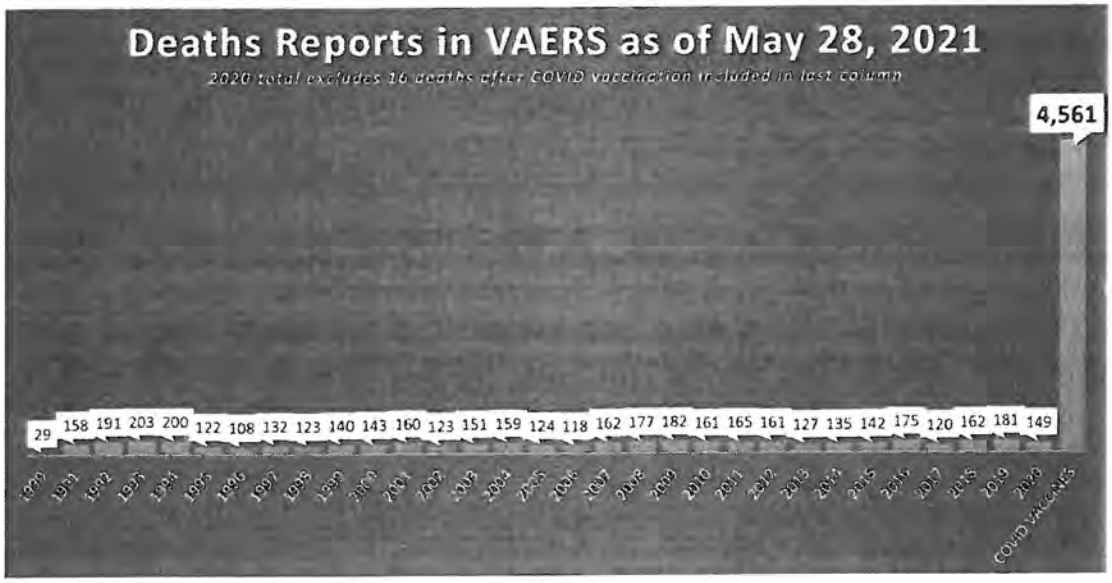
18. Thus, far, there are no prospective randomized double-blind placebo controlled randomized trials demonstrating clinical benefit, i.e., reductions in COVID-19 hospitalization and death. There are calls into the FDA advising not to approve the EUA COVID-19 vaccines for clinical use (Citizen Petition Urges FDA Against Premature Full Approval of Covid Vaccines Many open, unanswered questions surrounding the efficacy and safety of COVID-19 vaccines must be answered before the FDA considers granting a full approval, https://www.regulations.gov/document/FDA-2021-P-0521-0001).

19. The current COVID-19 vaccines are not sufficiently protective against contracting COVID-19 to support its use beyond the current voluntary participation in the CDC sponsored program. A total of 10,262 SARS-CoV-2 vaccine breakthrough infections had been reported from 46 U.S. states and territories as of April 30, 2021. Among these cases, 6,446 (63%) occurred in females, and the median patient age was 58 years (interquartile range = 40–74 years). Based on preliminary data, 2,725 (27%) vaccine breakthrough infections were asymptomatic, 995 (10%) patients were known to be hospitalized, and 160 (2%) patients died. Among the 995 hospitalized patients, 289 (29%) were asymptomatic or hospitalized for a reason unrelated to COVID-19. The median age of patients who died was 82 years (interquartile range = 71–89 years); 28 (18%) decedents were asymptomatic or died from a cause unrelated to COVID-19. Sequence data were available from 555 (5%) reported cases, 356 (64%) of which were identified as SARS-CoV-2 variants of concern, including B.1.1.7 (199; 56%), B.1.429 (88; 25%), B.1.427 (28; 8%), P.1 (28; 8%), and B.1.351 (13; 4%). None of these variants are encoded in the RNA or DNA of the current COVID-19 vaccines. In response to these numerous reports, the CDC announced on May 1, 2021, that community breakthrough cases would no longer be reported to the public and only those vaccine failure cases requiring hospitalization will be reported, presumably on the CDC website (https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm)

[10] Exhibit 4 – Baylor Scott & White Health Consent Form.

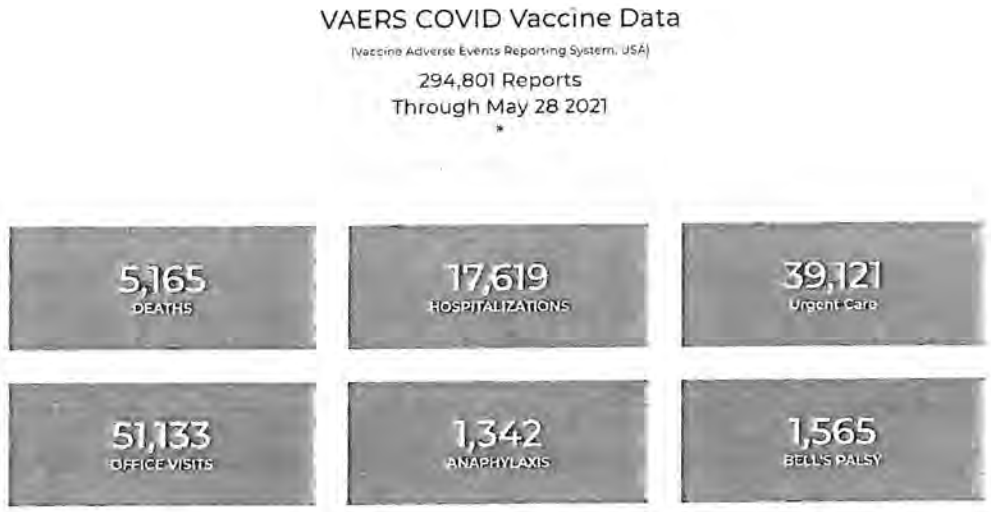
20. In 1990, the Vaccine Adverse Event Reporting Systems ("VAERS") was established as a national early warning system to detect possible safety problems in U.S. licensed vaccines.[11] VAERS is a passive reporting system, meaning it relies on individuals to voluntarily send in reports of their experiences to CDC and FDA. VAERS is useful in detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

21. Based on VAERS as of May 28, 2021, there were 5,165 deaths reported and over 17,619 hospitalizations reported. By comparison, from July 1, 1997, until December 31, 2013, VAERS received 666 adult death reports for all vaccines.[12] Following is a graphical representation of VAERS data:



[11]VAERS may be publicly accessed at https://www.openvaers.com/covid-data.

[12] Exhibit 5. Pedro L. Moro, Jorge Arana, Mria Cano, Paige Lewis, and Tom T. Shimabukuro, Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013, VACCINES, CID 2015:61 (September 2015).



22. Flu vaccines are linked to 20–30 death reports a year, and those 20–30 death reports come with considerably more vaccines administered. Arguably, if the experimental vaccine was any other vaccine or drug, it would already have been removed from the market. Usually, a new drug is withdrawn after 50 deaths, which is not typical because the FDA has a strict approval process. By comparison, the Swine Flu mass vaccine program in 1976 vaccinated 55 million of the nation's 220 million inhabitants and resulted in 500 cases of Gullian Barre syndrome and 25 total deaths and was withdrawn from use in what was reported to be a public health debacle.

23. With the current COVID-19 vaccines in EUA use since December 2020, a reported 5,165 deaths represents over 100 times the normal threshold for pulling a drug from the market. Although this is raw data, previous VAERS studies have shown that only 1-10% of vaccine-related deaths are reported to VAERS —or less.[13] The COVID vaccines are adding a year's worth of VAERS death reports every week. In just five months, more adverse reports were added to the VAERS database than any single vaccine has had cumulatively over the past 31 years. It is also interesting to note that 46% of deaths are estimated to occur 1-3 days after receipt of the first injection.

24. With approximately 50% of the US population vaccinated, mortality is not the only serious adverse event that has been reported after the COVID-19 vaccine largely by physicians and healthcare workers who are concerned the clinical event is related to the investigational COVID-19 vaccine. Additional morbidity reported to the CDC and verified with a permanent VAERS number include: 17,619 HOSPITALIZATIONS, 39,121 Urgent Care visits, 51,133 OFFICE VISITS, 1,342 cases of ANAPHYLAXIS, 1,565 cases of BELL'S PALSY, 5,317 Life Threatening events, 1,892 Heart Attacks, 756 cases of Myocarditis/Pericarditis, 1,392 cases

[13] https://www.openvaers.com/covid-data.

of Thrombocytopenia/Low Platelet, 571 Miscarriages, 13,574 Severe Allergic Reactions, 3,994 Disabling illnesses.[14]

25. The lack of safety of the COVID-19 vaccines is worldwide issue and a group of 57 authors from 17 countries has published a call for immediate risk mitigation with CEC, DSMB and IRB independent committees, otherwise halt the world wide programs. (https://www.authorea.com/users/414448/articles/522499-sars-cov-2-mass-vaccination-urgent-questions-on-vaccine-safety-that-demand-answers-from-international-health-agencies-regulatory-authorities-governments-and-vaccine-developers).

26. An important issue with the vaccines that is being ignored in the vaccine-enthused medical community is whether those people who have already contracted and recovered from SARS-COV-2 should receive the mRNA/adeno viral DNA vaccines. There are 3 published studies on this matter. [15] The conclusion is that for those with previous SARS-COV-2 a mRNA/adeno viral DNA is contraindicated and harmful since there is no opportunity for benefit and only an opportunity for harm. There are no published studies to the contrary, i.e., that the mRNA/adeno viral DNA vaccines are safe to take by those who have already had SARS-COV-2.

27. Raw et al. reported that in 974 individuals who received the BNT162b2/Pfizer vaccine, those with a prior history of SARS-CoV-2 or those who had positive antibodies at baseline, had a higher rate of vaccine reactions than those who were COVID-19 naive.[16]

28. Mathioudakis et al. reported that in 2002 patients who underwent vaccination with either mRNA-based, or vector-based COVID-19 vaccines, COVID-recovered patients who were needlessly vaccinated had higher rates of vaccine reactions.[17]

29. Krammer et al. reported on 231 volunteers for COVID-19 vaccination, 83 of whom had positive SARS-CoV-2 antibodies at the time of immunization. The authors found: "Vaccine recipients with preexisting immunity experience systemic side effects with a significantly higher frequency than antibody naïve vaccines (e.g., fatigue, headache, chills, fever, muscle or join pains, in order of decreasing frequency, $P < 0.001$ for all listed symptoms, Fisher's exact test, two-sided)." (https://doi.org/10.1101/2021.01.29.21250653).

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[14] https://www.openvaers.com/covid-data.

[15] Florian Krammer, Komal Srivastava, the PARIS team, and Viviana Simon, Robust Spike Antibody Responses and Increased Reactogenicity in Seropositive Individuals After a Single Does of SARS-COV-2 mRNA Vaccine, Feb. 1, 2021; Alexander G. Mathioudakis, Murad Ghrew, Andrew Ustianowski, Shazaad Ahmad, Ray Borrow, Lisa Pieretta Papavasileiou, Dimitrios Petrakis, Nawar Diar Bakerly, Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: An International Vaccine-Recipient Survey, March 8, 2021; Rachel K. Raw, Clive Kelly, Jon Rees, Caroline Wroe, and David R. Chadwick, Previous COVID-19 Infection by not Long-COVID is Associated with Increased Adverse Events Following BNT162b2/Pfizer Vaccination, April 22, 2021.

[16] *See* https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1.

[17] *See* https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1.

30. To my knowledge, there are no studies demonstrating clinical benefit of COVID-19 vaccination in COVID-19 survivors or those who have laboratory evidence of prior infection.

31. It is my opinion that SARS-CoV-2 causes an infection in humans that results in robust, complete, and durable immunity, and is superior to vaccine immunity. There are no studies demonstrating clinical benefit of COVID-19 vaccination in COVID-19 survivors and there are three studies demonstrating harm in such individuals. Thus, it is my opinion that the COVID-19 vaccination is contraindicated in COVID-19 survivors.

32. Overall, based on my 30 years in medicine, and in reviewing thousands of medical studies and abstracts, this is dangerous and uncharted territory in the medical field. Never before has an employer required an EUA product under clinical investigation without proven efficacy and safety, in a program without protection of human research subjects (EAC, DSMB, IRB). Participation in research is always voluntary and according to the Office of Human Research Protections and the Nuremberg Code, must be free of pressure, coercion (including offering money), and threat of reprisal (e.g. termination of employment). It is my opinion as a physician and active healthcare worker, there is no scientific or clinical support for any employer to mandate the participation of a clinical investigation of any COVID-19 vaccine(s) products as a condition of employment. The vaccines are not sufficiently protective, have not been shown to be clinically beneficial meaning no COVID-19 reduction in hospitalization and death, and have been found to have an unfavorable safety profile with unacceptably high rates of serious safety events including hospitalization and death after injection. No persons should be effectively forced into clinical research where the well-known possibility of serious adverse effects including death could occur as a result of being coerced against their will and right of autonomy over what is injected into their bodies.

33. I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED on June 9, 2021

P. McCullough June 9, 2021

Peter A. McCullough, MD, MPH